

SECTION 2 - 510(k) SUMMARY

K960479

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The device is substantially equivalent to the following legally marketed devices:

1. The Elecath® Ventricular Pacewedge® Pacing and Pressure Catheter, open tip, catalog no. 34-6567, from the Electro-Catheter Corporation, Rahway, NJ, Premarket Notifications K832850 and K844003.
2. A combination of two Arrow pre-enactment catheters, the Balloon Temporary Bipolar Pacing Catheter and the Balloon Wedge Pressure catheter.

The ARROW Bipolar Pacing/Balloon Wedge Pressure Catheter is made of radiopaque polymeric tubing marked in 10 cm increments. The catheter body contains two separate pressure lumens, and a balloon inflation lumen, which lie parallel to each other and then form separate extensions at the proximal end of the catheter. The pressure lumens have female Luer fittings at extensions at the proximal end of the catheter. The "distal" pressure lumen terminates in an opening at the distal tip of the catheter. The "proximal" pressure lumen terminates in an opening 29.5 cm, proximal to the tip. The catheter electrically conducts through the use of two 2 mm platinum electrodes, located at 14 and 15.2 cm from the distal tip. This connection terminates proximal to the molded juncture with two extension leads marked "d" for distal and "p" for proximal.

The ARROW catheter is indicated for use in sampling blood for oxygen levels and measuring pressure in the right heart (including central venous pressure, right ventricular pressure, pulmonary artery pressure, and pulmonary artery wedge pressure). The second pressure lumen allows infusion of a solution with simultaneous measurement of pressure. The catheter is intended for temporary use in electrophysiology studies for intracardiac simulation and/or ECG recording only.

The device has comparable technological characteristics to the predicate devices.

The nonclinical test results included in the submission comparable performance to the Elecath® device are as follows:

- Catheter flow rate testing
- Column strength test
- Balloon multiple inflation test
- Tube electrode torque test
- Catheter/electrode torque test
- Catheter body torque test
- Flexural modulus test
- Juncture lead pull test
- Electrical continuity test
- Signal to noise ratio test
- Impedance testing
- high pot test
- Catheter capacitance/inductance test
- Radiopacity testing